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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,749	01/14/2002	Michael Vajdy	16464.003	5494

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,749	VAJDY ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 33* is/are pending in the application.

4a) Of the above claim(s) *6,7 and 22-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-21, 29-30 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/16/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Reassignment Affecting Application Location

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Examiner Emily Le.

Status of Claims

2. Claims 1-30 and 33 are pending. Claims 31-32 and 34 are cancelled. Claims 6-7 and 22-28 are withdrawn from examination for being directed to a nonelected invention. Claims 1-5, 8-21, 29-30 and 33 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The rejection of claims 15 and 30 under the second paragraph of 35 U.S.C. 112 is withdrawn in view of Applicant's submission.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The rejection of claims 1-5, 8-21, 29-30 and 33 under the first paragraph, including both enablement and written description, of 35 U.S.C. 112 is withdrawn in view of Applicant's submission.

7. Claims 1-5, 8-21, 29-30 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant amended the claims requiring the multiple dose schedule to comprise a first course of administration comprising multiple doses followed by a second course of administration.

To provide support for the amended claim, Applicant cited lines 20-23 on page 35 and previously pending claims 31-34.

Lines 20-23 on page 35 of the specification provides the following: A multiple dose schedule is one in which a primary course of vaccination may be with 1-10 separate doses, followed by other doses given at subsequent time intervals, chosen to maintain and/or reinforce the immune response, for example at 1-4 months for a second dose, and if needed, a subsequent does(s) after several months.

In the instant, the language introduced in the claims is not completely supported by the language presented at lines 20-23 on page 35. No where within the cited passage is there an expressed, implicit or inherent support for the full language presented in the claims. In the instant, the cited passage provides sufficient support for a multiple dose schedule that consists of a primary course of vaccination, wherein the primary course of vaccination consists of 1-10 separate doses; and wherein the primary course of vaccination is followed by other doses given at subsequent time intervals. The cited passage does not provide a multiple dose schedule comprising a first course

of administration comprising more than 1-10 doses, and followed by a second course of administration.

Additionally, regarding claims 31-34, these claims are not part of the original disclosure. Thus, the use of language or limitations recited therein to support language presented in the current claims is not appropriate. Furthermore, even claims 31-34 are part of the original disclosure, or the language presented in claims 31-34 is supported by the original disclosure; it is found that the language presented in claims 31-34 does not fully support the language currently presented in the pending claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-5, 8-14, 16-21, 29-30 and 33 remain anticipated by Malone et al.[1]

In response to the rejection set forth in the previous office action, Applicant amended the claims to require the multiple dose schedule to comprise a first course of administration comprising multiple doses followed by a second course of administration.

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[1] Malone et al. U.S. Pat. No. 6110898, filed 05/23/1997.

Applicant's submission has been considered, however, it is not found persuasive. It should be noted that the language Applicant has presented in the claims, in an attempt to clarify the dosage regimen encompassed by the term "multiple dose schedule" is not supported by the originally filed disclosure. See the written description rejection provided above.

Applicant also submits that Malone does not describe or demonstrate multiple dose schedules, as claimed.

Applicant's submission has been considered, however, it is not found persuasive. At lines 15 *et seq.* of column 17 of Malone et al. writes, "priming, booster and maintenance dosing...will be suitable for use in the method of the invention." In the instant, Malone et al. teaches a multiple dose schedule that includes priming, booster and maintenance dosing. Thus, contrary to Applicant's submission, Malone et al. does describe multiple dose schedules.

Furthermore, the Office recognizes that Applicant may be arguing that the multiple dose schedule of Malone et al. does not include a primary course of vaccination that includes multiple doses. This point has been considered by the Office, however, Applicant is reminded that the specification does not excludes the use of a single dose as part of the primary course of vaccination. See lines 20-23, on page 35 of Applicant's specification. At the cited passage, Applicant provides that a multiple dose schedule consists of a primary course of vaccination, wherein the primary course of vaccination consists of 1-10 separate doses; and wherein the primary course of vaccination is followed by other doses given at subsequent time intervals. The cited passage does

not exclude the consideration of a single dose administration as part of a primary course of vaccination. Thus, in the instant, Malone et al. teaches a multiple dose schedule when Malone et al. teaches priming, booster and maintenance dosing.

Applicant also submits that the Office has not shown that Malone inherently discloses antigen presentation by dendritic cells.

Applicant's submission has been considered, however, it is not found persuasive. In the instant, Malone et al. teaches the claimed invention. Malone et al. teaches a method of generating an immune response in a subject using the same active method step as described in the claims, by mucosally administering the composition, and using the same active ingredient as described in the claims, a replication-defective gene delivery vehicle comprising a polynucleotide encoding at least one antigen. The difference between the claimed invention and the teachings provided by Malone et al. is: Malone et al. does not readily recognize the presentation of the antigen by dendritic cells. However, MPEP § 2113 [R-3](I) provides: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that

was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Id.< See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103. Hence, Malone et al. does not need to recognize the presentation of the antigen by dendritic cells to render the claimed invention unpatentable. In the instant, Applicant's discovery of a scientific explanation of the prior art's functioning does not render the claimed invention patentable.

10. Claims 1, 3, 5, 8-12, 18-20 and 31 remain anticipated by Belyakov et al.[2]

In response to the rejection set forth in the previous office action, Applicant amended the claims to require the multiple dose schedule to comprise a first course of administration comprising multiple doses followed by a second course of administration.

Applicant's submission has been considered, however, it is not found persuasive. It should be noted that the language Applicant has presented in the claims, in an attempt to clarify the dosage regimen encompassed by the term "multiple dose schedule" is not supported by the originally filed disclosure. See the written description rejection provided above.

Applicant also submits that Belyakov does not describe or demonstrate multiple dose schedules, as claimed.

Applicant's submission has been considered, however, it is not found persuasive. At the 4th full paragraph of the 1st column on page 8265, Belyakov et al. teaches:

"We used either a single dose of virus for immunization (intraperitoneal [i.p.] or i.r.) or one single dose plus one boosting dose (of $1x10^7$ or $1x10^8$ PFU) for i.r. immunization."

In the instant, Belyakov et al. teaches a multiple dose schedule that includes one single dose plus one boosting dose. Thus, contrary to Applicant's submission, Belyakov et al. does describe multiple dose schedules.

Furthermore, the Office recognizes that Applicant may be arguing that the multiple dose schedule of Belyakov et al. does not include a primary course of vaccination that includes multiple doses. This point has been considered by the Office, however, Applicant is reminded that the specification does not excludes the use of a single dose as part of the primary course of vaccination. See lines 20-23, on page 35 of Applicant's specification. At the cited passage, Applicant provides that a multiple dose schedule consists of a primary course of vaccination, wherein the primary course of vaccination consists of 1-10 separate doses; and wherein the primary course of vaccination is followed by other doses given at subsequent time intervals. The cited passage does not exclude the consideration of a single dose administration as part of a primary course of vaccination. Thus, in the instant, Belyakov et al. teaches a multiple dose schedule when Belyakov et al. teaches one single dose plus one boosting dose.

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[2] Belyakov et al. Induction of a mucosal cytotoxic T-lymphocyte response by intrarectal immunization with a replication–deficient recombinant vaccinia virus expressing human immunodeficiency virus 89.6 envelope protein. J. Virol, October 1998, Vol. 72, 10, 8264-8272.

11. Claims 1-2, 5, 8, 11-12, 18-20 and 31 remain anticipated by Kano et al.[3]

In response to the rejection set forth in the previous office action, Applicant amended the claims to require the multiple dose schedule to comprise a first course of administration comprising multiple doses followed by a second course of administration.

Applicant's submission has been considered, however, it is not found persuasive. It should be noted that the language Applicant has presented in the claims, in an attempt to clarify the dosage regimen encompassed by the term "multiple dose schedule" is not supported by the originally filed disclosure. See the written description rejection provided above.

Applicant also submits that Kano does not describe or demonstrate multiple dose schedules, as claimed.

Applicant's submission has been considered, however, it is not found persuasive. At the 3rd paragraph, Kano et al. teaches 3 inoculations, on weeks 0, 4 and 14. In the instant, Kano et al. teaches a multiple dose schedule that includes i) one single dose followed by two more doses; or ii) two doses followed by one more dose. Thus, contrary to Applicant's submission, Kano et al. does describe multiple dose schedules.

Furthermore, the Office recognizes that Applicant may be arguing that the multiple dose schedule of Kano et al. does not include a primary course of vaccination that includes multiple doses. This point has been considered by the Office, however, Applicant is reminded that the specification does not excludes the use of a single dose as part of the primary course of vaccination. See lines 20-23, on page 35 of Applicant's

[3] Kano et al. Induction of SIV-specific cellular immune responses by using recombinant sendai viral

specification. At the cited passage, Applicant provides that a multiple dose schedule consists of a primary course of vaccination, wherein the primary course of vaccination consists of 1-10 separate doses; and wherein the primary course of vaccination is followed by other doses given at subsequent time intervals. The cited passage does not exclude the consideration of a single dose administration as part of a primary course of vaccination. Thus, in the instant, Kano et al. teaches a multiple dose schedule when Kano et al. 3 inoculations, on weeks 0, 4 and 14; wherein the 3 inosculations are part of a multiple dose schedule that includes i) one single dose followed by two more doses; or ii) two doses followed by one more dose.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 15 remains obvious over Malone et al.

In response to the rejection set forth in the previous office action, Applicant submits that Malone does not teach or suggest a multiple dosing schedule as claimed.

Applicant's submission has been considered, however, it is not found persuasive. It should be noted that the language Applicant has presented in the claims, in an attempt to clarify the dosage regimen encompassed by the term "multiple dose

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vector. 7th Conf. Retrov. and Opportun. Inf., 2000.S

schedule" is not supported by the originally filed disclosure. See the written description rejection provided above.

Additionally, at lines 15 *et seq.* of column 17 of Malone et al. writes, "priming, booster and maintenance dosing...will be suitable for use in the method of the invention." In the instant, Malone et al. teaches a multiple dose schedule that includes priming, booster and maintenance dosing. Thus, contrary to Applicant's submission, Malone et al. does describe multiple dose schedules.

Furthermore, the Office recognizes that Applicant may be arguing that the multiple dose schedule of Malone et al. does not include a primary course of vaccination that includes multiple doses. This point has been considered by the Office, however, Applicant is reminded that the specification does not excludes the use of a single dose as part of the primary course of vaccination. See lines 20-23, on page 35 of Applicant's specification. At the cited passage, Applicant provides that a multiple dose schedule consists of a primary course of vaccination, wherein the primary course of vaccination consists of 1-10 separate doses; and wherein the primary course of vaccination is followed by other doses given at subsequent time intervals. The cited passage does not exclude the consideration of a single dose administration as part of a primary course of vaccination. Thus, in the instant, Malone et al. teaches a multiple dose schedule when Malone et al. teaches priming, booster and maintenance dosing.

Applicant also submits that the Office ahs not provided any reason or evidence as to why one of ordinary skill in the art would have been motivated to modify Malone to

arrive at the claimed invention since Malone does not teach or suggest alphavirus vectors including sequences from two or more alphaviruses.

Applicant's submission has been considered, however, it is not persuasive.

As presented in the previous office action, the Office acknowledges that Malone et al. does not expressly teach a method wherein the gene delivery vehicle comprises elements (i.e. gene constructs) from two or more alphaviruses. However, this limitation provides that a sequence from the alphavirus gene delivery vehicle, such as a promoter, may be substituted with a sequence from an alphaviruses of different serotype. Whether the gene delivery vehicle is derived from one or two alphavirus genomes is immaterial since both embodiments would have a similar structure and function. Thus, modifying Malone's gene delivery to include a second construct would have been obvious to one of ordinary skill in the art.

In the instant, MPEP § 2144.06, SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE provides: In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (The mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components. However, an applicant's expressed recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist.); In re Scott, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow

fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.). An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to have to substitute the promoter sequence of an alphavirus serotype with the promoter sequence of an alphavirus of another serotype. And the motivation, which was inherently expressed in the previous office action, to make a gene delivery vehicle.

Conclusion

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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06/05/06